United States Court of Appeals for the Federal Circuit

CELGENE CORPORATION,
Plaintiff-Appellant

v.

MYLAN PHARMACEUTICALS INC., MYLAN INC., MYLAN N.V.,
Defendants-Appellees

2021-1154

Appeal from the United States District Court for the District of New Jersey in No. 2:19-cv-05802-ES-MAH, Judge Esther Salas.

Decided: November 5, 2021

ELLYDE R. THOMPSON, Quinn Emanuel Urquhart & Sullivan, LLP, New York, NY, argued for plaintiff-appellant. Also represented by FRANCIS DOMINIC CERRITO, FRANK CHARLES CALVOSA, ERIC C. STOPS; MATTHEW J. HERTKO, Jones Day, Chicago, IL; JENNIFER L. SWIZE, Washington, DC.

TUNG ON KONG, Wilson, Sonsini, Goodrich & Rosati, PC, San Francisco, CA, argued for defendants-appellees. Also represented by KRISTINA M. HANSON; STEFFEN

NATHANAEL JOHNSON, GEORGE E. POWELL, III, Washington, DC; ELHAM FIROUZI San Diego, CA.

Before PROST, CHEN, and HUGHES, *Circuit Judges*.

PROST, *Circuit Judge*.

This is a case about venue and pleading under the Hatch-Waxman Act.

Celgene Corporation ("Celgene") markets pomalidomide as a multiple-myeloma drug under the brand name Pomalyst. It has patents related to that drug, but many drug companies viewed the validity or applicability of those patents with skepticism and sought to bring generic pomalidomide to market. They applied to the FDA to do so; Celgene sued. This appeal concerns Celgene's suit surrounding the abbreviated new drug application ("ANDA") submitted by Mylan Pharmaceuticals Inc. ("MPI").

Celgene filed that suit in New Jersey. Celgene is headquartered there, but none of the defendants are. Rather, MPI is based in West Virginia, Mylan Inc. in Pennsylvania, and Mylan N.V. in Pennsylvania and the Netherlands. The district court ultimately dismissed this case for improper venue (as to MPI and Mylan Inc.) and for failure to state a claim (as to Mylan N.V.). Celgene appeals.

For the reasons below, we agree with the district court that venue was improper in New Jersey for the domestic-corporation defendants, MPI and Mylan Inc. That is, Celgene did not show that those defendants committed acts of infringement in New Jersey and have a regular and established place of business there. We also agree that, as to the foreign-corporation defendant, Mylan N.V., Celgene's pleadings failed to state a claim upon which relief could be granted. We therefore affirm.

I

A

In 1984, Congress enacted the Hatch-Waxman Act, a complex statutory framework that tries to balance generic and brand interests within the pharmaceutical industry. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585. One aim of Hatch-Waxman was to "speed the introduction of low-cost generic drugs to the market." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

To market a new drug, a sponsor submits to the FDA a new drug application ("NDA"). *See Caraco*, 566 U.S. at 404. An NDA must contain the drug's proposed labeling and directions for use but also must contain extensive information on clinical trials showing that the drug is safe and effective for its labeled use. *See id.* Brand-drug sponsors are also required to inform the FDA of all its patents covering the drug or its labeled methods of use. *See* 21 U.S.C. § 355(b)(1), (c)(2). These patents are publicly listed in what is known as the Orange Book. *Caraco*, 566 U.S. at 405–06.

To speed the introduction of low-cost generics, Hatch-Waxman includes the option for generic-drug sponsors to submit an abbreviated new drug application, or ANDA. With an ANDA, a generic-drug sponsor need not repeat a brand drug's safety-and-efficacy trials at great (and scientifically redundant) expense. Instead, a generic-drug sponsor must show that its product is bioequivalent to the reference brand drug. *See id.* If so, the sponsor can market that generic drug with a label matching that of brand drug. *See id.* at 415, 425.

A generic-drug sponsor may not market a drug in a way that infringes a brand-drug sponsor's patents. *See id.* at 405–06; *FTC v. Actavis, Inc.*, 570 U.S. 136, 143 (2013).

The generic must therefore "assure the FDA" that marketing the generic "will not infringe." *Actavis*, 570 U.S. at 143. It does so through certifications to the FDA.

An ANDA applicant might choose to avoid infringement by waiting out a patent's term. If so, the applicant includes with its ANDA a so-called paragraph III certification for that patent. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(III). It might also omit a patented method of use from its drug label and therefore not seek approval in a way that implicates the patent. *See* 21 U.S.C. § 355(j)(2)(A)(viii); *Caraco*, 566 U.S. at 406–07, 425; *United Food & Com. Workers Local 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co.*, 11 F.4th 118, 124–27 (2d Cir. 2021). But an applicant might also think that a patent is invalid, unenforceable, or not infringed, notwithstanding its ANDA encompassing the same methods of use as the brand drug's NDA. If so, the applicant can ask for full approval (without omitting any methods of use from its drug label) during the patent's term and include with its ANDA a paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Submitting an ANDA that seeks approval to market a drug while that drug is on-patent (e.g., an ANDA containing a paragraph IV certification) is patent infringement. 35 U.S.C. § 271(e)(2); *see also Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc.*, 978 F.3d 1374, 1381–82 (Fed. Cir. 2020).[1] If a generic goes the paragraph IV route, the brand can sue under a set of rules particular to this kind of infringement. The way this works is that the generic must

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[1] That is not to say that a generic's failure to comply with some procedural rule surrounding the paragraph IV certification renders an ANDA noninfringing. The statutory infringement question is whether the "purpose" of the submitted ANDA "is to obtain approval" to market the drug "before the expiration of [the relevant] patent." 35 U.S.C. § 271(e)(2).

provide a so-called paragraph IV notice to the patentee brand-drug sponsor after it submits its ANDA and the FDA confirms receipt of the submission. *See* 21 U.S.C. § 355(j)(2)(B); *see also id.* § 355(j)(2)(B)(ii)(I). That notice must include "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(iv)(II). The notice and accompanying detailed statement, however, are not part of the ANDA and need not be submitted to the FDA. *See id.*; 21 C.F.R. § 314.95(e). Indeed, the substance of the notice letter (i.e., the generic's legal opinion) is immaterial to the FDA, which professes to lack "expertise" and "authority" on patent matters. *See Caraco*, 566 U.S. at 406–07; *United Food*, 2021 WL 3744899, at *3; Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,683 (June 18, 2003) ("[W]e have long observed that we lack expertise in patent matters.").

A brand-drug sponsor that sues within 45 days of receiving notice of a generic's paragraph IV certification is entitled to an automatic thirty-month stay of FDA approval so the infringement and validity questions can be worked out in court. 21 U.S.C. § 355(j)(5)(B)(iii); *Actavis*, 570 U.S. at 143. If a brand-drug sponsor waits more than 45 days after it receives notice, it isn't entitled to that stay but also isn't precluded from suing later for infringement. *See, e.g.*, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1325 (Fed. Cir. 2021); *Dey Pharma, LP v. Sunovion Pharms. Inc.*, 677 F.3d 1158, 1160 (Fed. Cir. 2012); *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1341 (Fed. Cir. 2007); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1297 n.5 (11th Cir. 2003). If the brand-drug sponsor doesn't sue within the 45 days, the generic can instead bring a declaratory-judgment action "to obtain patent certainty." 21 U.S.C. § 355(j)(5)(C)(i); 35 U.S.C. § 271(e)(5); *see Dey Pharma*, 677 F.3d at 1160–61; *Teva*, 482 F.3d at 1335. The upshot is that the timing

of receipt of the notice letter governs the timing of the availability of particular forms of relief.

B

In early 2017, MPI submitted an ANDA seeking approval to market a generic version of Pomalyst before the expiration of four Orange-Book-listed patents. MPI included a paragraph IV certification as to those patents. In turn, Celgene sued the defendants under the Hatch-Waxman Act, asserting the four listed patents.

Celgene later obtained (and asserted) five more related patents. It sued the same defendants again twice—once in 2018, asserting one of the later-issued patents, and once in 2020, asserting another. Those cases were consolidated with the 2017 one. For the sake of simplicity, we call that consolidated six-patent action "the first case."[2] In 2019, Celgene asserted the remaining three of the later-issued patents (again against these defendants, again in New Jersey) through a largely identical complaint. That's *this* case.[3] This procedural bookkeeping matters because this case, though not consolidated with the first, shared Rule 12 briefing with it. That is, the parties stipulated that the resolution of motions to dismiss in the first case would govern this one too. *See* J.A. 220–23.

Celgene filed its first case in May 2017. The defendants-appellees moved to dismiss for improper venue and failure to state a claim in August 2017. That motion was denied in March 2018 without prejudice so that the parties could engage in venue-related discovery.

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[2] *Celgene Corp. v. Hetero Labs Ltd.*, No. 17-cv-3387 (D.N.J.).

[3] *Celgene Corp. v. Mylan Pharms.*, No. 19-cv-5802 (D.N.J.).

After two years of that discovery, the defendants renewed their motion to dismiss. The district court reviewed the motion under *In re Cray Inc.*, 871 F.3d 1355 (Fed. Cir. 2017), and concluded that venue was improper. Namely, the thin set of facts that Celgene had gathered after those two years—the presence of affiliated entities and employees in New Jersey—failed to show a "regular and established place of business" of the defendants in the district under 28 U.S.C. § 1400(b).

The district court also concluded that, for Mylan N.V., Celgene had failed to state a claim upon which relief could be granted. That is, the ANDA that Celgene itself included with its complaint sought approval only on behalf of MPI. And Celgene's pleadings with respect to the involvement of Mylan N.V. in that submission were simply too speculative and conclusory. In doing so, the district court also rejected Celgene's request in the alternative for leave to amend its pleadings.

Celgene appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

II

First we turn to the district court's dismissal of MPI and Mylan Inc. for improper venue.

We review de novo whether venue under § 1400(b) is proper.[4] *Valeant*, 978 F.3d at 1381. The plaintiff has the burden of establishing proper venue under that provision. *Andra Grp., LP v. Victoria's Secret Stores, L.L.C.*, 6 F.4th 1283, 1287 (Fed. Cir. 2021).

To establish venue, a plaintiff may show either that the defendant "resides" in a particular district or that it "has committed acts of infringement and has a regular and

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[4] Federal Circuit law applies to this issue, which is unique to patent law. *Valeant*, 978 F.3d at 1381.

established place of business" there. 28 U.S.C. § 1400(b).[5] No one argues that the defendants-appellees reside in New Jersey. And so Celgene has the burden of meeting both portions of the other prong of § 1400(b)—that is, showing both the defendants' acts of infringement in the district and their regular and established place of business there. The district court concluded that it had not met that burden with respect to MPI and Mylan Inc. For the reasons below, the district court was correct.

A

First, we address whether MPI and Mylan Inc. "committed acts of infringement" in New Jersey. We conclude that they did not.

1

As we have repeatedly observed, "the Supreme Court has instructed that the requirement of venue is specific and unambiguous; it is not one of those vague principles [that], in the interests of some overriding policy, is to be given a liberal construction." *Andra*, 6 F.4th at 1287 (cleaned up)

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[5] Celgene also argues—largely on policy grounds—that venue in Hatch-Waxman cases should be governed by 28 U.S.C. § 1391(c), the general venue provision. But *TC Heartland* and *Valeant* say otherwise. The Supreme Court in *TC Heartland* reaffirmed that § 1400(b) is the sole and exclusive provision controlling venue in patent infringement actions. *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1519 (2017). And this court in *Valeant* reiterated that submitting an ANDA is an act of infringement for purposes of § 1400(b). 978 F.3d at 1381–82. It follows that § 1400(b) is the sole venue provision with respect to domestic defendants in Hatch-Waxman actions. *See also Valeant*, 978 F.3d at 1382 ("Congress enacted § 1400(b) in 1948 to be a standalone venue statute for patent cases.").

(citing *Schnell v. Peter Eckrich & Sons, Inc.*, 365 U.S. 260, 264 (1961)); *see also In re Google LLC*, 949 F.3d 1338, 1346 (Fed. Cir. 2020) ("[T]he Supreme Court has cautioned against a broad reading of the venue statute."). Time and again "we have narrowly construed the requirements of venue in patent cases." *Valeant*, 978 F.3d at 1379.

This court in *Valeant* recently addressed venue under Hatch-Waxman. We reiterated that "venue in Hatch-Waxman cases must be predicated on past acts of infringement." *Valeant*, 978 F.3d at 1381. And for the purposes of the Hatch-Waxman Act, "it is the submission of the ANDA, and only the submission, that constitutes an act of infringement in this context." *Id.* In so holding, we expressly rejected relying on the contemplated future conduct of the generic-drug sponsor. *Id.* at 1381–83.

2

Celgene argues that the defendants have committed acts of infringement in New Jersey. Here, the alleged infringing act is the submission of the ANDA. *See* 35 U.S.C. § 271(e)(2); *Valeant*, 978 F.3d at 1381. The question is where the submission occurred and what acts it includes.

First, Celgene argues that the "artificial act of infringement stemming from the ANDA submission extends nationwide" (i.e., wherever the generic drug will be marketed and sold). Relatedly, it contends that the effects of the ANDA submission will be "felt" in New Jersey. But *Valeant* squarely forecloses Celgene's position. Venue must be "predicated on past acts of infringement." *Valeant*, 978 F.3d at 1381. For Hatch-Waxman cases, this means venue is proper "where an ANDA-filer submits its ANDA to the FDA," not "wherever future distribution of the generic is contemplated." *Id.* at 1378–79; *see also id.* at 1384.

Second, Celgene argues that, because MPI sent a paragraph IV notice letter from West Virginia to Celgene's headquarters in New Jersey, acts of infringement occurred

in New Jersey. The notice letter is mandatory and the ANDA must be amended later to include proof that it was delivered. *See* 21 C.F.R. § 314.95(a), (e). So, says Celgene, receipt of the letter by the brand sponsor is part of the "act of infringement" for venue purposes. We disagree.

This court in *Valeant* stated that "[u]nder the plain language of the statute, the only past infringing act is the ANDA submission, which creates the right to bring suit in the first instance." 978 F.3d at 1382. Celgene argues that infringement for venue purposes includes all "acts that are 'sufficiently related to the ANDA submission.'" *See, e.g.*, Appellant's Br. 48, 50, 51 (quoting *Valeant*, 978 F.3d at 1384). Celgene is incorrect. While the court took care not to prematurely "define what all relevant acts involved in the preparation and submission of an ANDA might be," *Valeant*, 978 F.3d at 1384 n.8, it did make clear that it is the *submission* that infringes, *id.* at 1381–82. *Valeant*'s focus on the submission itself (along with acts involved in its "preparation") indicates that the relevant infringing acts must, at a minimum, fairly be *part of* the submission—not merely "related to" it in some broader sense. *See id.* at 1384 (considering whether "acts occurred" in the district "that would suffice to categorize those taking them as a 'submitter' under § 271(e)"). After all, the relevant prong of § 1400(b) restricts venue to "where the defendant has committed acts of infringement"—not where the defendant has committed acts related to (but not part of) acts of infringement. *See Valeant*, 978 F.3d at 1381 ("[I]t is the submission of the ANDA, and only the submission, that constitutes an act of infringement in this context.").

With this in mind, we turn to Celgene's argument that receipt of the notice letter is an infringing act in New Jersey. Celgene says that the notice letter is an "essential part of the ANDA submission" itself, Appellant's Br. 50, and that the defendants "had to undertake an act in New Jersey to fulfill its requirements for its ANDA submission," Reply Br. 25. But the statute and regulations treat the

infringing ANDA submission and the notice letter as different things. For example, the initial ANDA submission to the FDA requires the applicant to state that it "will give notice"—and such notice "shall" be given "not later than 20 days after" the date that the FDA confirms that the ANDA has been filed. 21 U.S.C. § 355(j)(2)(B)(i), (ii)(I); 21 C.F.R. § 314.95(b)(1). Indeed, the ANDA applicant cannot send the notice letter before the FDA has confirmed receipt of the ANDA. 21 C.F.R. § 314.95(b)(2). The notice letter itself is even required to state that an ANDA "has been submitted." 21 U.S.C. § 355(j)(2)(B)(iv); 21 C.F.R. § 314.95(c)(1) (specifying that "the notice must include," among other things, "[a] statement that [the] FDA has received an ANDA submitted by the applicant"). And the applicant is under no obligation to send a copy of the notice letter itself to the FDA. 21 C.F.R. § 314.95(e) ("A copy of the notice itself need not be submitted to the Agency."); *id.* § 314.95(b)(3) (similar). Further, one statutory provision separately references "the date on which the [paragraph IV] notice is received" and "the date on which the application . . . was submitted." 21 U.S.C. § 355(j)(5)(B)(iii). Under the statute and regulations, then, receipt of the notice letter occurs after and apart from the submission of the ANDA.

Celgene argues that infringement under 35 U.S.C. § 271(e)(2) occurs only once the ANDA filing contains a paragraph IV certification—and therefore that receiving the notice letter is part of the infringing act because it "triggers the patent owner's infringement claim." Appellant's Br. 49–50. We disagree. First, as we explained above, the paragraph IV certification in the ANDA *precedes* the notice letter. And although receipt of the letter influences the timing of the lawsuit by setting a 45-day cutoff after which the patentee cannot get an automatic 30-month stay of final approval, the letter itself does not establish the cause of action. The ANDA submission does. The statute itself says that it is an act of infringement to "submit . . . an

[ANDA] application" "if the purpose . . . is to obtain approval" to market the drug "before the expiration of" a relevant patent. 35 U.S.C. § 271(e)(2). Celgene points to no authority suggesting either that an ANDA with noncompliant notice doesn't infringe or that it can never sue for infringement if the generic doesn't comply with the formalities of the notice provision.

Under § 271(e)(2), submitting an ANDA is the act of infringement. And although the ANDA applicant must later send a notice letter and inform the FDA of the letter's receipt, that all happens *after* the infringing submission. Sending a paragraph IV notice letter does not fall within "submitting" the ANDA under the meaning of *Valeant*. Accordingly, we conclude that Celgene did not establish that the defendants-appellees committed an act of infringement in New Jersey.

B

Next we address whether MPI and Mylan Inc. had a "regular and established place of business" in New Jersey. We conclude that they did not.

1

To show that a defendant has a regular and established place of business, there are three requirements: "(1) there must be a physical place in the district; (2) it must be a regular and established place of business; and (3) it must be the place of the defendant." *Cray*, 871 F.3d at 1360. Venue is improper if any of those three is not satisfied. *See id.*

The third requirement is particularly relevant here. The place must be "of the defendant, not solely . . . of the defendant's employee." *Id.* at 1362–63. Accordingly, "the defendant must establish or ratify the place of business," and it is "not enough that the employee does so on his or her own." *Id.*

We have observed that in the venue inquiry "no precise rule has been laid down and each case depends on its own facts." *Id.* at 1362. But as to the third requirement, we have discussed non-exhaustive relevant factors, including (1) "whether the defendant owns or leases the place, or exercises other attributes of possession or control over the place"; (2) "whether the defendant conditioned employment on" "an employee's continued residence in the district" or "the storing of materials at a place in the district so that they can be distributed or sold from that place"; (3) "a defendant's representations" about that place, including advertisements; and (4) "the nature and activity of the alleged place of business of the defendant in the district in comparison with that of other places of business of the defendant in other venues." *Id.* at 1363–64.

2

No one argues that either MPI or Mylan Inc. itself has any fixed, physical presence in New Jersey. Instead, Celgene offers two theories to impute venue to those defendants: first, through places associated with Mylan employees, and second, through places associated with Mylan affiliates. We discuss each in turn.

i

First, Celgene contends that certain employee-associated locations should be imputed to MPI and Mylan Inc.

Celgene first points to a handful of homes in New Jersey. Those homes belong to MPI or Mylan Inc. employees. In total, MPI and Mylan Inc. have tens of thousands of employees. Seventeen live in New Jersey. J.A. 2311 The defendants-appellees also presented evidence that neither MPI nor Mylan Inc. (1) required or instructed those employees to live in New Jersey, (2) pays for their homes, (3) requires the employees to store materials in the homes or in New Jersey, or (4) pays for secretarial or support staff

to work at the homes. J.A. 2311. These specific facts went undisputed. J.A. 57–58.

Celgene argues that MPI and Mylan Inc.'s representations to the public show that the homes are places of the defendants. But Celgene doesn't point to advertising or marketing identifying the personal homes as places of business. And even if it had, the fact "that a defendant has advertised that it has a place of business or has even set up an office is not sufficient; the defendant must actually engage in business from that location." *Cray*, 871 F.3d at 1364.

Celgene instead points to a roster of employees who live in the state, a handful of business cards with employee names and New Jersey home addresses, and two LinkedIn profiles mentioning New Jersey. Without more, this is all too speculative to show ratification of those addresses as MPI's or Mylan Inc.'s places of business (much less that the employees themselves regularly conducted business specifically at their homes). Indeed, it is not enough "that there exists within the district a physical location where an employee of the defendant carries on certain work for his employer." *Id.* at 1366.

Celgene also identifies a job posting (listing no specific Mylan entity) asking that candidates live in New Jersey or "within reasonable driving distance."[6] *See, e.g.*, J.A. 2549–51. The undated posting does little to illuminate MPI's or Mylan Inc.'s employment requirements in 2017. Indeed, we agree with the district court that the record shows no requirement to actually live in New Jersey or any restriction on moving out of state once there. *See* J.A. 60–61. And we have observed that an employee's

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[6] The district court properly disregarded several other job postings as being insufficiently relevant, being unrelated to New Jersey in 2017. *See* J.A. 60 n.5.

ability to move "out of the district at his or her own instigation, without the approval of the defendant . . . cut[s] against the employee's home being considered a place of business of the defendant." *Cray*, 871 F.3d at 1363.

At bottom, this case is like *Cray*. There, the defendant did not rent or own an office or any property in the district, but it allowed two employees to work remotely from their homes there. *Cray*, 871 F.3d at 1357. The company identified the employees' home numbers in business communications, and they worked as local territory managers and sales executives in the region. *See id.* But the company did not maintain products at their homes, the company did not pay for their homes, and no one advertised their homes as the company's place of business. *Id.* Similarly, MPI and Mylan Inc. "allowed" its employees to work from the district. But there was "no indication" that MPI or Mylan Inc. "own[], lease[], or rent[]" their homes, that they "played a part in selecting the [homes'] location, stored inventory or conducted demonstrations there, or conditioned . . . employment or support on the maintaining of" a home in New Jersey. *See id.* at 1365. And even if evidence here might suggest that MPI or Mylan "believed a location within [New Jersey] to be important to the business performed," there is no evidence that MPI or Mylan Inc. "had any intention to maintain some place of business in that district" if the employees were to "decide[] to terminate their residences." *Id.* In view of the specific evidence here, the employee homes here are not places "of the defendant."[7]

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[7] Celgene argues for the first time on appeal that "the fact that service of process could be effectuated on MPI and Mylan Inc. at their employees' homes" confirms that § 1400(b) is satisfied. *See* Appellant's Br. 38. Celgene doesn't dispute that it didn't raise this point at the district court. Reply Br. 17. The underlying record on this point is, accordingly, underdeveloped, and the appellees

Beyond the homes, Celgene also points to two small storage lockers rented by MPI sales or marketing employees to store product samples. Those lockers are rented in the employees' own names. They are used to intermittently store and access product samples. There is no evidence, in contrast, that they are used like warehouses—for order fulfillment, wholesaling, retail, or the like. As the appellees point out, Celgene offered no evidence that MPI or Mylan

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maintain that Celgene has forfeited this argument. *See In re Google Tech. Holdings LLC*, 980 F.3d 858, 862–63 (Fed. Cir. 2020). We agree, and we are also skeptical on the merits. Even if we accepted Celgene's argument that some employees could accept service of process on behalf of the defendants at their homes, Celgene has not demonstrated that this would make the employees' homes the defendant's place of business. The patent service provision, 28 U.S.C. § 1694, states that an agent "conducting" the defendant's business can accept service in a district in which the defendant "has a regular and established place of business." But courts considering the question have held that § 1694 is not the exclusive basis for service of process in a patent-infringement action. Rule 4 of the Federal Rules of Civil Procedure provides for service of process not necessarily predicated on a regular and established place of business of the defendant. *See, e.g.*, *Welch Sci. Co. v. Human Eng'g Inst., Inc.*, 416 F.2d 32, 34 (7th Cir. 1969); 14D Wright & Miller, *Federal Practice & Procedure* § 3823 (4th ed., Apr. 2021 update). We therefore tend to agree with the appellees that, although the presence of a defendant's regular and established place of business in a district implies that service is proper on agents there, the presence of employees who can accept service does not by itself establish the existence of the defendant's regular and established place of business at those employees' location. Regardless, given Celgene's argument forfeiture and evidentiary failures, we need not decide the issue.

Inc. requires its employees to store materials anywhere in New Jersey or that renting lockers in New Jersey was anything but the employees' choice. Nor did Celgene offer any evidence that either MPI or Mylan Inc. owns, leases, possesses, or controls the lockers. And Celgene hasn't pointed to any advertisements or other representations holding them out as places of MPI or Mylan Inc.

Celgene mainly points to testimony that some employees needed to access the lockers "as part of [their] job." But even if MPI or Mylan Inc. required employees to have access to pharmaceutical samples (wherever they ended up being stored), no evidence suggests that they were required to specifically use lockers in New Jersey in the first place. Accordingly, the testimony cites does not support a reasonable inference that MPI or Mylan Inc. established or ratified New Jersey–based lockers as a place of business. In our view, then, the lockers are not places "of the defendant." Nor do they bolster that the employees' homes were such places, as Celgene suggests in the alternative.

Celgene finally argues that even if the homes or lockers cannot *individually* be considered regular and established places of business, they should *together* be deemed as much. But even setting aside that Celgene points to no case endorsing its aggregate-place theory—one in which we would "assess[] venue on a district-by-district rather than address-by-address basis," Appellant's Br. 41—we are unconvinced that the homes and lockers even lumped together would be "of the defendant" under the facts of this case.

In summary, the employee-associated locations are not a regular and established place of business of the defendants under § 1400(b).

ii

In the alternative, Celgene emphasizes that a now-defunct entity—Mylan Laboratories Inc. ("MLI")—had a

physical office in New Jersey. In its view, that office should be imputed to MPI and Mylan Inc. for venue purposes. We disagree.

MLI, before it dissolved in 2017, was a Delaware corporation with an office in New Jersey. J.A. 68. Through a chain of ownership, it was indirectly wholly owned by MPI. J.A. 68.

At the district court, Celgene argued an alter-ego theory predicated on the defendants' disregard of corporate formalities, contending that all the Mylan entities were effectively operating as a single company. J.A. 62, 3154. In the alternative, it argued that a showing of alter ego or abuse of the corporate form wasn't required. J.A. 62.

The district court was not convinced. It surveyed various cases, concluding that the majority view is that a subsidiary's presence isn't imputed to a parent for venue unless the parties "disregarded the corporate form in their dealings with their respective subsidiaries and affiliates." J.A. 66. And that wasn't shown, the district court concluded. We agree.

Venue may be imputed under an alter-ego or veil-piercing theory. *See Andra*, 6 F.4th at 1289; *Minn. Min. & Mfg. Co. v. Eco Chem, Inc.*, 757 F.2d 1256, 1265 (Fed. Cir. 1985) ("*3M*"). But "where related companies have maintained corporate separateness, the place of business of one corporation is not imputed to the other for venue purposes." *Andra*, 6 F.4th at 1289. Corporate separateness is an issue of regional-circuit law. *See Wechsler v. Macke Int'l Trade, Inc.*, 486 F.3d 1286, 1295 (Fed. Cir. 2007). The relevant veil-piercing theory in the Third Circuit is called the "alter ego" doctrine, among other names. *See Pearson v. Component Tech. Corp.*, 247 F.3d 471, 484 & n.2 (3d Cir. 2001). Under that doctrine, courts will disregard the corporate form to "prevent fraud, illegality, or injustice," "when recognition of the corporate entity would defeat public policy or shield someone from liability for a crime," or "when

the parent so dominated the subsidiary that it had no separate existence." *Id.* at 484 (first quoting *Zubik v. Zubik*, 384 F.2d 267, 272 (3d Cir. 1967); and then quoting *N.J. Dep't of Env't Prot. v. Ventron Corp.*, 468 A.2d 150, 164 (N.J. 1983)).[8] Among other possible considerations, the Third Circuit looks at "gross undercapitalization, failure to observe corporate formalities, nonpayment of dividends, insolvency of the [subsidiary] corporation, siphoning of funds from the [subsidiary] corporation by the dominant stockholder, nonfunctioning of officers and directors, absence of corporate records, and whether the corporation is merely a facade for the operations of the dominant stockholder." *Id.* at 484–85 & n.2; *see also Trinity Indus., Inc. v. Greenlease Holding Co.*, 903 F.3d 333, 365 (3d Cir. 2018). In the end, this is an inquiry into whether the entities' separateness "is little more than a legal fiction"—a "notoriously difficult" burden. *Pearson*, 247 F.3d at 485. Plaintiffs "must essentially demonstrate that in all aspects of the business, the two corporations actually functioned as a single entity." *Id.* A court "consider[s] whether veil piercing is appropriate in light of the totality of the circumstances." *Trinity Indus.*, 903 F.3d at 365.

Against this standard, Celgene's factual offerings come up short. Namely, Celgene pointed to shared marketing, branding, and trade names, as well as MLI's involvement in procuring pomalidomide for ANDA preparation (as well as other unspecified preparatory aspects). Appellant's

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[8] The appellees argued and the district court concluded that there must also be a showing of "extraordinary circumstances, such as fraud or injustice." Appellees' Br. 32 (citing *Linus Holding Corp. v. Mark Line Indus., LLC*, 376 F. Supp. 3d 417, 425 & n.4 (D.N.J. 2019)); J.A. 67, 75 (similar). Because Celgene fails to show a disregard of corporate separateness, we need not reach that issue of Third Circuit law.

Br. 44 (citing J.A. 2487–88, 2494–96, 2499, 2534); J.A. 69–70. It also pointed to a Mylan Inc. employee signing MLI's lease termination when it dissolved and directing future correspondence to it. Appellant's Br. 44 (citing J.A. 2410, 2517, 2528); J.A. 69–70. But "courts have refused to pierce the veil even when subsidiary corporations use the trade name of the parent, accept administrative support from the parent, and have a significant economic relationship with the parent." *Pearson*, 247 F.3d at 485. Celgene also points out that MLI's sole officer was also an officer of Mylan Inc. and that the corporations all sit in a common web of ownership. Appellant's Br. 43–44 & n.7 (citing J.A. 2405–06, 2408, 2531–32). But it is a "well established principle" of corporate law "that directors and officers holding positions with a parent and its subsidiary can and do 'change hats' to represent the two corporations separately, despite their common ownership." *United States v. Bestfoods*, 524 U.S. 51, 69 (1998); *Trinity Indus.*, 903 F.3d at 367 ("[D]uplication of some or all of the directors or executive officers is not fatal to maintaining legally distinct corporate forms." (cleaned up)). And as the district court observed, there is no evidence showing, for instance, dominion of MLI's finances, policy, or business practices. *See* J.A. 67. Nor did Celgene show that MLI is "undercapitalized or insolvent, that its officers and directors are strawmen, or that MLI lacks its own books and records." *See* J.A. 70–71.

At most, the evidence shows collaboration, not commonality. Celgene has not met its burden of showing that corporate separateness has not been maintained with respect to MLI.[9]

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[9] Celgene points to various instances of possible form-blurring between MPI, Mylan Inc., and Mylan N.V. *E.g.*, Appellant's Br. 46–47 (discussing mutual review of ANDA filing and instance of reporting of single employee of one entity to employee of another). In our view, however,

Celgene alternatively argues that there is enough interrelatedness here, even absent a showing of alter ego, to impute venue wholesale from a subsidiary to its parent. *See* Appellant's Br. 43. But Celgene's cited cases do not support this view.

First, Celgene argues that this court in *3M* said that "the acts of another, intimately connected, corporation" could be enough to import venue across the board, "even absent a showing of alter ego." *See* Appellant's Br. 43. But that misreads *3M*. That case remarked that a "piercing the corporate veil" theory could be appropriate to impute venue. *3M*, 757 F.2d at 1265. It also commented that "infringement within the district by a wholly owned subsidiary can be considered infringement by the parent corporation for the purposes of [venue if] fraud upon or injustice to the plaintiff are present." *Id.* at 1265. It explained that the "corporate form is not readily brushed aside" and that "alter ego" is applied only if the record "clearly support[s] disregard of the corporate fiction on grounds of fundamental equity and fairness." *Id.* at 1264. And, importantly, in that case this court *did* find alter ego. *See id.* at 1264–65 (basing alter-ego finding on lack of corporate formalities and manipulation of form to thwart recovery of judgment).

Second, Celgene relies on *Leach*. *See Leach Co. v. Gen. Sani-Can Mfg. Corp.*, 393 F.2d 183, 184 (7th Cir. 1968). But the *Leach* court *also* found alter ego. *See id.* And there, the entities in question "did not observe even the form of corporate separation," and "freely disregarded their separateness" in practice, under the specific facts of that case. *Id.* at 186. And so *Leach* too provides no support for Celgene's alter-ego-free venue-imputation argument.

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this evidence does not move the needle on whether the corporate form was disregarded as to those firms *and MLI*.

Third, Celgene cites a handful of district-court cases for the proposition that showing alter ego or veil-piercing isn't necessary. *E.g.*, Appellant's Br. 43 (citing *Javelin Pharm., Inc. v. Mylan Labs. Ltd.*, No. 16-cv-224, 2017 WL 5953296, at *3–4 (D. Del. Dec. 1, 2017)); J.A. 65. We agree with the district court, however, that these cases answered a different question: whether the patentee stated a "non-frivolous basis to warrant venue-based discovery." *See* J.A. 65.

In all, Celgene's cited cases don't support the wholesale imputation of venue here. And Celgene has identified no authority showing that affiliation or shared activities alone are enough.

Of course, it might be that a parent corporation might specifically ratify a subsidiary's place of business, even if the two do maintain corporate separateness. *See, e.g.*, *Andra*, 6 F.4th at 1289. But Celgene hasn't argued that MPI or Mylan Inc. ratified MLI's New Jersey office.[10] Nor has Celgene argued that MLI's office was MPI's or Mylan Inc.'s under an agency theory. *See* J.A. 63; *Andra*, 6 F.4th at 1287–89.

In conclusion, Celgene has not met its burden to show a lack of corporate separateness such that MLI's place of business should be imputed to the defendants—nor provided any other reason to disregard the corporate distinction between them. And Celgene has not otherwise shown that MPI and Mylan Inc. established or ratified MLI's New Jersey office. Accordingly, that office is not a regular and

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[10] Celgene appears to have broadly argued that Mylan N.V. (for which venue would be proper) ratified the "collective business of Mylan entities conducted at physical places in the district." *See* Appellant's Br. 45. But it didn't argue this as to MPI or Mylan Inc., and, as discussed later, Celgene didn't adequately state a claim against Mylan N.V. anyway.

established place of business of the defendants under § 1400(b).

* * *

As in *Cray*, we stress that "each case depends on its own facts" and that, here, "no one fact is controlling." 871 F.3d at 1362, 1366. "But taken together, the facts cannot support a finding that" the defendants "established a place of business in" New Jersey. *See id.* Venue is therefore not proper as to MPI and Mylan Inc. under § 1400(b).

III

We move next from the propriety of venue to the adequacy of the pleadings. The district court dismissed Celgene's complaint against Mylan N.V. for failure to state a claim. It also denied Celgene's request in the alternative for leave to amend that complaint. We agree on the first point and conclude that the district court did not abuse its discretion on the second.

A

The district court dismissed Celgene's complaint against Mylan N.V. for failure to state a claim under Rule 12(b)(6), holding that Celgene hadn't made any nonconclusory allegations that Mylan N.V. "submitted" the ANDA under the meaning of 35 U.S.C. § 271(e)(2).

We review a dismissal under Rule 12(b)(6) de novo.[11] *Tatis v. Allied Interstate, LLC*, 882 F.3d 422, 426 (3d Cir. 2018). A complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)); *see also Bell Atl. Corp. v. Twombly*, 550 U.S.

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[11] Regional-circuit law applies to this issue. *Intell. Ventures I LLC v. Erie Indemnity Co.*, 850 F.3d 1315, 1325 (Fed. Cir. 2017).

544, 570 (2007). "Plausibility means 'more than a sheer possibility that a defendant has acted unlawfully.'" *Tatis*, 882 F.3d at 426 (quoting *Iqbal*, 556 U.S. at 678). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. At bottom, the pleading standard "does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Id.* at 678–79. Accordingly, we accept as true factual allegations in the plaintiff's complaint and all reasonable inferences that can be drawn from them, and we construe them in the light most favorable to the nonmovant. *Tatis*, 882 F.3d at 426. That said, we "disregard rote recitals of the elements of a cause of action, legal conclusions, and mere conclusory statements." *James v. City of Wilkes-Barre*, 700 F.3d 675, 679 (3d Cir. 2012). "[A] document integral to or explicitly relied upon in the complaint may be considered without converting the motion to dismiss into one for summary judgment." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (cleaned up).

As an initial matter, it is undisputed that MPI, not Mylan N.V., was the entity that signed and physically submitted the ANDA.[12] The question, then, is whether Celgene pled sufficient facts that either (1) Mylan N.V. was actively involved in and directly benefited from the ANDA (including in the agent–principal sense) or (2) MPI acted as

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[12] Celgene argues that the district court erroneously made formal signatory status dispositive. We disagree. The district court simply noted that Mylan N.V. hadn't signed the ANDA, as evidenced by the documents that Celgene itself included with the complaint. J.A. 80. Accordingly, Celgene cannot argue that Mylan N.V. filed the ANDA, despite its broad allegation that the Mylan defendants collectively "filed" the ANDA. J.A. 79–80.

Mylan N.V.'s alter ego in derogation of the corporate form. Celgene's pleadings fail under either theory.

Celgene alleged that MPI was wholly owned by Mylan Inc., and Mylan Inc. by Mylan N.V. J.A. 116–17 ¶¶ 6–7, 3057 ¶¶ 23–24. This chain of ownership alone, however, is insufficient to state a claim against Mylan N.V. based on MPI's ANDA submission. *See Pearson*, 247 F.3d at 484 ("[M]ere ownership of a subsidiary does not justify the imposition of liability on the parent."). And Celgene's remaining relevant allegations are, as the district court observed, too conclusory. Celgene alleged that the defendants "work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products." J.A. 120 ¶ 23 (present-case complaint), 3069 ¶ 76 (first-case complaint). It alleged that MPI "acts at the direction, and for the benefit, of Mylan N.V. and Mylan Inc., and is controlled and/or dominated by Mylan N.V. and Mylan Inc." J.A. 120 ¶ 24, 3069 ¶ 77. It alleged that unspecified "members of the Mylan corporate family" are "alter egos" of Mylan N.V. J.A. 121 ¶ 25. It also alleged that MPI was an "alter ego[]" of Mylan N.V. J.A. 119 ¶ 18. And it alleged that "Mylan" (defined collectively to include all three defendants) "filed Mylan's ANDA" at issue. J.A. 115–16 ¶ 1, 121–22 ¶ 30; *see also* J.A. 3074 ¶ 98. It also included with its complaint documents from the ANDA in question, which were filed and signed by MPI.

That just isn't enough. At most, Celgene's allegations amount to legal conclusions as to the defendants as a group—not to facts showing a plausible inference of liability as to Mylan N.V. For instance, nothing in the complaint suggests *how* Mylan N.V. is involved in the ANDA process, *how* it bypassed the corporate form to make MPI its alter ego, or the like.

Celgene points to the *Rosuvastatin* line of cases and argues both that signatory status does not matter and that

its allegations that Mylan N.V. will benefit should be enough. We disagree. As an initial matter, Celgene grossly overreads *Rosuvastatin*. *See In re Rosuvastatin Calcium Pat. Litig.*, 703 F.3d 511 (Fed. Cir. 2012). That case did not hold a non-signer liable or provide that benefiting from the ANDA was enough to be deemed to have "submitted" it. Instead, the entity that *signed* the ANDA sought to *escape* liability because it claimed that it was only filing the ANDA as the agent of a Canadian company. *Id.* at 527. And there, the entity in question not only signed the ANDA but was found to have participated in its preparation and represented that it would sell the product. *Id.* at 529. Accordingly, *Rosuvastatin* held that an entity that is actively involved in filing the ANDA *and* stands to benefit from its approval is a "submitter"—not that benefiting from it is enough alone. Against the backdrop of the ANDA itself—which names only MPI—Celgene provides no nonconclusory allegations that Mylan N.V. was actively involved in and would benefit from the ANDA's submission. Instead, it offers only "unadorned supposition" that the defendants "work in concert," *see* J.A. 79, and allegations that Mylan N.V. "filed" the ANDA that are contradicted by the ANDA itself.

Celgene further suggests that its allegations that Mylan N.V. directs and controls MPI (or that MPI is Mylan N.V.'s alter ego) should be enough, especially in view of the Mylan corporate structure. On these conclusory pleadings, we are unconvinced. As the district court observed, the complaint doesn't contain "specific facts with respect to how" this control occurs. J.A. 79; *cf. Twombly*, 550 U.S. at 556–57 (finding insufficient "conclusory allegation of agreement" and "bare assertion of conspiracy"). Again, the complaint in this case is too conclusory to establish a plausible claim of liability as to Mylan N.V. Were it otherwise, an allegation that one corporation filed an ANDA coupled with a bare assertion of cooperation or control by another

would open the door to discovery for the entire parent-subsidiary chain in any Hatch-Waxman case.

Finally, Celgene points to *Valeant*, in which the court remanded for a district court to consider the sufficiency of seemingly similar allegations, rather than dismissing the case outright. But the district court in *Valeant* hadn't decided the sufficiency of those allegations on the merits. There had been no adjudication *at all* on failure to state a claim. And so, rather than decide that issue, this court remanded to the district court to consider the allegations' sufficiency in the first instance, to resolve internally contradictory aspects of those allegations, and to consider whether leave to amend would be appropriate to clarify the confusion caused by those internally contradictory assertions. *Valeant*, 978 F.3d at 1384–85. Here, there has already been an initial adjudication and the issue is ready for appellate review.

We agree with the district court that Celgene did not state a claim against Mylan N.V.

B

At the district court, Celgene asked in the alternative for leave to amend to "add additional allegations regarding the interconnectedness of [the defendants], including with respect to their involvement in Mylan's ANDA." *See* J.A. 81 n.12. The district court denied Celgene's request.

We review the denial of leave to amend for abuse of discretion.[13] *Premier Comp Sols., LLC v. UPMC*, 970 F.3d 316, 318–19 (3d Cir. 2020). "Ultimately, a motion to amend is committed to the 'sound discretion of the district court.'" *In re Allergan ERISA Litig.*, 975 F.3d 348, 356 n.13 (3d Cir.

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[13] Regional-circuit law applies. *See Simio, LLC v. FlexSim Software Prods., Inc.*, 983 F.3d 1353, 1358 (Fed. Cir. 2020).

2020) (quoting *Cureton v. NCAA*, 252 F.3d 267, 272 (3d Cir. 2001)).

Ordinarily, Rule 15 of the Federal Rules of Civil Procedure sets a liberal standard that a court "should freely give leave" to amend "when justice so requires." But once the district court's scheduling-order deadline has passed, Rule 16(b)(4) kicks in and a party must first show good cause. *Premier Comp Sols.*, 970 F.3d at 319. No good cause, no leave to amend.

Celgene did not make its request in a way that was compliant with the district court's local rules. The district court also observed that the relevant amendment deadline had long since expired. And it noted that Celgene had been on notice of Mylan N.V.'s challenge to the adequacy of its pleading since August 2017 when the original motion to dismiss was filed.[14] Yet Celgene had not offered any grounds that demonstrated good cause for modification of the deadline. It denied Celgene's request.

On appeal, Celgene does not argue that it demonstrated good cause at the district court. Instead, it mainly (and incorrectly) argues that the district court considered the wrong deadline and didn't properly apply the Rule 15 standard. Recall that this was the second of two similar cases, as we explained above. *See supra* Section I.B. And

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[14] Celgene suggests that it wasn't on notice of this insufficiency because the district court initially denied the motion to dismiss. Appellant's Br. 27. But as to failure to state a claim, the district court simply didn't reach that ground on the merits—having allowed the parties to proceed on venue-related discovery instead. *See Celgene Corp. v. Hetero Labs Ltd.*, No. 17-cv-3387, ECF No. 150, at 8 (D.N.J. Mar. 2, 2018). It should have been no surprise that the ground was included when the defendants renewed their motion to dismiss.

recall that the parties stipulated that the resolution of Rule 12 motions in the first case would govern this one. *See id.* Celgene now argues that the *second* case's scheduling order (which had not expired when it made this leave-to-amend request in the *first* case) should apply. But the parties agreed that the resolution of the motion in the first case would govern this one. It would make little sense to apply the scheduling order in the second case when all the briefing occurred under the first case's schedule (and, indeed, the opinion that we're reviewing was *issued* in the first case). We also note that Celgene did not argue at the district court that the second case's scheduling order should apply—this argument is new on appeal. We conclude that the district court applied the correct deadline.

Celgene's allegations in its complaint were conclusory and insufficient. It knew the basis for their deficiency for years, as the district court correctly concluded, yet made no attempt to amend them in a timely manner. Nor has Celgene argued on appeal that it showed good cause. In our view, then, the district court did not abuse its discretion in denying Celgene's request for leave to amend its complaint.

IV

We have considered Celgene's remaining arguments but find them unpersuasive. For the reasons we discussed, the district court's judgment is affirmed.

AFFIRMED